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Exagen Settles FCA Case for Restitution, Paid Physicians Specimen Fees Despite OIG Alert

By Nina Youngstrom

In the second recent False Claims Act (FCA) case that ended with restitution, Exagen Inc.—a life sciences company that makes diagnostic tests for autoimmune conditions—agreed to pay $653,143 to settle allegations it gave kickbacks to referring physicians in the form of specimen processing fees, the U.S. Attorney's Office for the District of Massachusetts said Oct. 17.[1]

"It's unusual in my experience that there is a dollar-for-dollar payback in addition" to a release from the relator's FCA claims and the government's common-law theories of payment by mistake, unjust enrichment and fraud, said former federal prosecutor Robert Trusiak. With restitution as opposed to double or triple damages, the company gets a tax benefit, said Trusiak, with Trusiak Law in Buffalo, New York.

According to the settlement, many physicians and medical groups ordered Exagen lab tests to help diagnose autoimmune conditions. Exagen paid some referring physicians to do blood draws for patients under specimen processing agreements (SPAs) between June 25, 2014, and June 21, 2021.[2] Exagen billed Medicare for tests it performed after receiving orders from the referring physicians who were paid specimen processing fees under the SPAs.

The HHS Office of Inspector General (OIG) on June 25, 2014, released the Special Fraud Alert on Laboratory Payments to Referring Physicians, which "indicated that these arrangements could present a substantial risk of fraud and abuse under the Anti-Kickback Statute [AKS]."[3] Exagen ended its physician referral arrangements by June 21, 2021, and doesn't have these types of agreements with referring physicians anymore, according to the settlement.

Exagen admitted and accepted responsibility for those facts. Its attorney declined to comment. The settlement noted that "Exagen shall pay to the United States $653,143 (the 'Settlement Amount'), of which $653,143 is restitution, and interest on the Settlement Amount at a rate of 3.625% per annum…"

The FCA lawsuit was set in motion by a whistleblower, Omni Healthcare, Inc., a multispecialty physician group in Brevard County, Florida. Its complaint alleged that Exagen mentioned OIG's special fraud alert in a Sept. 18, 2019, prospectus it filed with the Securities and Exchange Commission before it became a public company.[4]

Because the U.S. Department of Justice only partially intervened in its case, Omni will continue its FCA lawsuit against Exagen on the remaining allegations by itself, said its attorney, Sean Estes of Hoyer Law Group PLLC in Tampa, Florida. "This is a partial settlement and the relator is going forward on claims that weren't covered by the settlement," he said. As for the settlement dollars, Estes said although "you see settlements for double damages, in this case the government found the restitution amount to be reasonable for the covered conduct it was settling." Estes noted that the relator's plans to move forward are "probably not factored in much to the government's settlement decision-making."

Whistleblower Inquired About 'Referral Fees'

Omni filed the FCA complaint in 2021 and amended it last year "to add defendants John Does 1-10," but the amended complaint was still unavailable as of Oct. 20. According to the first version, Omni entered into an SPA with Exagen in late 2014. "The SPA called for a 'referral fee,' disguised as a specimen collection fee, of $10 for each specimen the relator sent to the defendant," the complaint alleged. From the time the SPA was signed though April 6, 2016, about 129 specimens were submitted to Exagen, which allegedly paid Omni $1,290 for the specimens.

After that, Omni didn't submit specimens to Exagen for the referral fee through 2019, the complaint alleged. In late 2019, Omni contacted Exagen to check whether it was still paying referral fees for specimen collection. The whistleblower alleged it "knew that if defendant was still paying 'referral fees,' even though they claimed in their prospectus that the practice had ceased, they were violating the AKS."

According to the complaint, on Oct. 7, 2019, a provider relations supervisor for Exagen sent Omni an updated SPA and Omni started submitting specimens to Exagen, allegedly to gather evidence that it was violating the AKS. Exagen allegedly offered $20 per specimen collected.

An 'Unusual' Resolution

Trusiak thinks there's more to this story than what's alleged in the complaint and settlement. "It's unusual to have direct evidence of apparent wrongdoing" but only restitution, he said. Would labs or other providers be dissuaded by this settlement from remunerating physicians, or would they be incentivized? "It seems to me you are incentivized. Why? I might never get caught and if I get caught, I just have to pay back single damages and get tax benefits and a FCA release [from the relator] to boot," Trusiak said. The two things prosecutors are required to do are punishment and deterrence, he said. "Here it seems to me it's reasonable to question how either of those principles were advanced. What have you punished? What have you deterred? I'm just asking questions. I have full respect for my former brethren in U.S. attorneys' offices."

Although the government didn't release its FCA claims, "as a matter of practicality, the government is not going to pursue its False Claims Act claims and Exagen received a full False Claims Act release from the only person who could bring" an FCA lawsuit based on the covered conduct again: the relator, Trusiak said. Exagen also was released by the government for the common-law theories of liability.

The U.S. attorney's office in Massachusetts declined to comment.

Another FCA settlement with restitution—but much larger dollars and FCA releases from the government—came down Oct. 10. Cardiac Imaging Inc. (CII), a mobile cardiac PET scan provider, and its owner/CEO have agreed to pay $85.48 million to settle false claims allegations that they paid kickbacks to referring cardiologists in the form of excessive supervision fees.[5] In separate settlements, CII agreed to pay $75 million and CEO Sam Kancherlapalli will fork over $10 million. On top of the $75 million, CII will pay the government annual interest plus 45% of its gross revenue exceeding $64 million annually for five years, according to the settlement.[6] "The Settlement Amount, interest received by the United States, and Revenue Sharing...constitute restitution."

'It's a Pretty Tough Needle to Thread'

Former OIG Senior Counsel David Traskey said OIG has had concerns dating back to the mid-1990s about labs offering anything of value to referral sources. The Special Fraud Alert cited in the Exagen case "addresses arrangements under which laboratories pay physicians, either directly or indirectly (such as through an arrangement with a marketing or other agent) to collect, process, and package patients' blood specimens

(Specimen Processing Arrangements)." OIG warns that certain characteristics of specimen processing arrangements may implicate the AKS.

Based on what's in the fraud alert and the Exagen complaint and settlement, Traskey said he finds OIG's position "tricky." OIG is concerned both "when labs provide free or below market goods and services to physicians who are referral sources and pay more than fair-market value for physician services or for services the lab doesn't need or for which physicians are already being compensated," said Traskey, with Garfunkel Wild P.C. in Washington, D.C. OIG also isn't comfortable if the lab tries to carve out federal health care program beneficiaries from arrangements because "they can still give rise to incentives for labs to refer federal health care program beneficiaries," as it indicated in a recent advisory opinion, he said.[7] "My takeaway is it's a pretty tough needle to thread."

Providers may be better off "confidently" fitting into a safe harbor for personal services arrangements, management contracts or outcomes-based payment and a Stark Law exception, Traskey said. "If I put my OIG hat on, the third option is always—to the extent you want an extra layer of comfort—to seek an advisory opinion."

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1 U.S. Department of Justice, U.S Attorney's Office for the District of Massachusetts, "Exagen Inc. Agrees to Pay $653,143 to Resolve Allegations of Kickback Violations," news release, October 17, 2023, https://bit.ly/3s3rY4U.
2 Settlement agreement, United States, et al., ex rel. Omni Healthcare, Inc. v. Exagen, Inc., No. 21-cv-10950 (D. Mass., 2023), https://bit.ly/45IxXtM.
3 U.S. Department of Health and Human Services, Office of Inspector General, "Special Fraud Alert: Laboratory Payments to Referring Physicians," June 25, 2014, https://bit.ly/3Q6O3I5.
4 Complaint, United States, et al., ex rel. Omni Healthcare, Inc. v. Exagen, Inc., No. 21-cv-10950 (D. Mass., 2021), https://bit.ly/48VkZvH.
5 U.S. Department of Justice, Office of Public Affairs, "Mobile Cardiac PET Scan Provider and Founder to Pay $85 Million to Resolve Allegedly Unlawful Payments to Referring Doctors," news release, October 10, 2023, https://bit.ly/3RQSrgK.
6 Settlement agreement, U.S. ex rel. Pinto v. Cardiac Imaging, Inc., et al., No. 18-cv-2674 (S.D. Tex., 2023), https://bit.ly/3ttwhXQ.
7 Nina Youngstrom, "In Another Unfavorable Advisory Opinion, OIG KOs Lab Deal; Requester Again Wanted a No," *Report on Medicare Compliance* 32, no. 35 (October 2, 2023), https://bit.ly/46VdHWX.